

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, new claim 28 has been added. Support for this new claim can be found throughout the originally filed application. Thus, no new matter has been added.

Turning now to the Office Action mailed on April 19, 2005, it is noted that this Office Action is a non-final action. In this non-final Office Action, the Examiner has made the following four rejections:

- (i) Claim 4 has been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Kodera et al. (United States Patent No. 4,366,125) in view of DiGeronimo (United States Patent No. 4,494,357) and further in view of Lologer et al. (United States Patent No. 3,692,468);
- (ii) Claims 2-3, 5, 15, 17 and 21-26 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Kodera et al. (United States Patent No. 4,366,125) in view of DiGeronimo (United States Patent No. 4,494,357);
- (iii) Claim 6 has been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Kodera et al. (United States Patent No. 4,366,125) in view of DiGeronimo (United States Patent No. 4,494,357) as applied to claim 21 and further in view of Lagunas-Solare et al. (United States Patent No. 5,364,645); and

- (iv) Claim 18 and 27 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Kodera et al. (United States Patent No. 4,366,125) in view of DiGeronimo (United States Patent No. 4,494,357) as applied to claim 26 and further in view of Castberg et al. (United States Patent No. 5,744,094).

All of these rejections are respectfully traversed.

In each of these rejections, the Examiner has utilized the same primary and secondary references – KODERA in view of DIGERONIMO. Both of these references were previously relied upon by the Examiner albeit in a different order. However, the order in which these references are utilized by the Examiner does not change the fundamental flaw in the Examiner's position. Such flaw is the failure to recognize that even when hydrogen peroxide is removed from the packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light. The technique of Kodera et al. and the other references cited by the Examiner, exemplify the technically inferior solutions used for the last twenty years by the entire packaging industry, which failed to arrive at the present invention, despite the long-felt need.

In making the rejections under 35 U.S.C. § 103(a), the Examiner makes reference to the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148, USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a). These factual enquiries are briefly considered:

1. Determining the scope and contents of the prior art.

The prior art teaches that in order to sterilize a material, one must apply peroxide and irradiate with UV light, prior to removal of the peroxide. This is logical and expected since the well-known synergy between peroxide and UV light inherently requires the presence of peroxide and UV to carry out a sterilization process. This is described at page 4 in the originally filed application, which refers to U.S. Patent No. 4,289,728 to Peel et al. This synergy is very well known and has been used as standard practice in the industry for over twenty years.

2. Ascertaining the differences between the prior art and the claims at issue.

As pointed out in the responses to the six previous Office Actions, the prior art fails to teach the sequential combination of steps claimed in this application, *i.e.*, (1) applying peroxide to a material to be sterilized, (2) removing peroxide from the material to be sterilized, and only after the removal of the peroxide, and (3) irradiating the material with UV light. The prior art fails to recognize that even when hydrogen peroxide is removed from the packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light. Prior to the present invention, it was not understood that the sequential steps claimed in the present application could function. (See the enclosed presentation material that explains the differences between the prior art and the invention in Annex 1, and the explanations in the scientific publication enclosed as Annex 2).

3. Resolving the level of ordinary skill in the pertinent art.

The level of ordinary skill in the art has been exemplified by the numerous references cited by the Examiner in his previous Office Actions when they are considered singularly. By combining the references with the benefit of hindsight, and

without any suggestion in the prior art itself to make such combinations, the Examiner has constrained applicant to take account of a level of skill that goes well beyond the ordinary level of skill in the art. And still, one cannot derive therefrom any teaching to make the invention as claimed in the present application, *i.e.*, to irradiate material to be sterilized with UV light, only after removal of peroxide from the material by drying.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicant's claimed invention exploits the inventor's discovery that even when hydrogen peroxide is removed from a packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light. Several scientific articles, clearly explain the concept that, even if the synergistic effect of H<sub>2</sub>O<sub>2</sub> and UV light was well known, it was unobvious, and certainly not known to one of ordinary skill in the pertinent art, that the microorganisms were able to absorb hydrogen peroxide:

- (i) Reidmiller et al., "Characterization of UV-Peroxide Killing of Bacterial Spores" *Journal of Food Protection*, 66(7):1233-40 (2003) (copy enclosed -- see Annex 2);
- (ii) Bayliss et al. "The synergistic killing of spores of *Bacillus subtilis* by hydrogen peroxide and ultraviolet light irradiation", *FEMS Microbiol. Lett.*, 5: 331-33 (1979);

- (iii) Bayliss et al., "The combined effect of hydrogen peroxide and ultraviolet irradiation on bacterial spores", *J. Appl. Bacteriol.*, 47, 263-69 (1979); and
- (iv) Bagyan et al., "The *katX* gene, which codes for the catalase in spores of *Bacillus subtilis*, is a forespore-specific gene controlled by  $\delta^F$ , and *KatX* is essential for hydrogen peroxide resistance of the germinating spore", *J. Bacteriol.*, 180, 2057-62 (1998).

#### **THE EXAMINER'S OBVIOUSNESS REJECTION OF CLAIM 4**

Claim 4 has been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over KODERA in view of DIGERONIMO and further in view of LOLIGER.

Initially, it is noted that the Examiner has isolated specific portions of the KODERA patent and interpreted them out of context with respect to the KODERA patent considered in its entirety. KODERA discloses a sequence of removing dust from a web in a chamber 11, applying a thin film of peroxide to the web (see column 1, line 68 et seq.) in a mist atmosphere chamber 12, irradiating the web with the peroxide thereon with UV lamps 34, then drying the web with a drying chamber 41. Claim 1 of KODERA recites a sterilization apparatus comprising a plurality of housings communicatively connected in sequence:

- hydrogen peroxide sterilizing means
- ultra-violet-ray sterilization means in a housing downstream in said travel direction from the hydrogen peroxide sterilizing means
- drying means in a housing downstream from the ultra-violet-ray sterilization means.

There is no suggestion in KODERA to locate the drying means upstream of the ultra-violet-ray sterilization means nor any other teaching that would lead one of ordinary skill in the art to practice the method claimed in claim 4, without hindsight of the present invention.

Additionally, as discussed above, there is no suggestion in KODERA (or any of the other references cited by the Examiner) that when hydrogen peroxide is removed from the packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light. Claim 4 specifically recites as element of the claim that a stream of air is applied to the packaging material "for removing a substantial amount of hydrogen peroxide from the surface of the packaging sheet material while retaining a residual or trace quantity of hydrogen peroxide absorbed by or located adjacent to any microorganisms present on said packaging sheet material . . . ." (Emphasis added). In attempting to address this element of claim 4, since every element of the claims must be taught or suggested by the prior art for there to be a proper prima facie case of obviousness, the Examiner has argued that "the microorganisms present on the surfaces of the packaging sheet material in the Koder reference intrinsically absorb the residual hydrogen peroxide left after the step of drying." OFFICE ACTION at 3 (emphasis added).

Intrinsically is simply another word for inherently. However, the concept of inherency is not applicable to and has no place in an obviousness rejection. Inherency and obviousness are distinct concepts. In re Spormann, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966) ("The inherency of an advantage and its

obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.").

Accordingly, a proper prima facie case of obviousness has been established since there is no teaching or suggestion in the Koder a et al. reference, nor any other reference cited by the Examiner, that a stream of air is applied to the packaging material "for removing a substantial amount of hydrogen peroxide from the surface of the packaging sheet material while retaining a residual or trace quantity of hydrogen peroxide absorbed by or located adjacent to any microorganisms present on said packaging sheet material . . . ." (Emphasis added).

The Examiner has attempted to combine the disclosure of KODERA with the disclosure of DIGERONIMO. In particular, the Examiner has indicated that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Koder a reference by irradiating at 254 nm as taught by the DiGeronimo reference since the lamp at such a wavelength operates at 99.9% efficiency (col.2, lines 50-52)." However, even if one modified the apparatus of KODERA to include UV lamps operating at 254nm as taught by DIGERONIMO, the resulting apparatus would still not operate with sequential combination of steps claimed in this application, *i.e.*, (1) applying peroxide to a material to be sterilized, (2) removing peroxide from the material to be sterilized, and only after the removal of the peroxide, (3) irradiating the material with UV light.

The Examiner has also attempted to combine the disclosure of LOLIGER for the proposition that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Koder a reference by heating the hydrogen peroxide bath to 60 degree Celsius as taught by the Loliger

reference since it is known in the art that at such a temperature packing sheet residence time in the bath is only 6 second that even kills heat-resistant germs (col. 1, lines 30-33)".

However, even if one further modified the apparatus of KODERA including UV lamps operating at 254nm as taught by DIGERONIMO, to substitute the means 12,13 for applying a thin film of peroxide to the web in a mist atmosphere chamber 12 with a peroxide bath at 60 degrees Celsius in the manner suggested by the Examiner, the resulting apparatus would still not operate with sequential combination of steps claimed in the present application, *i.e.*, (1) applying peroxide to a material to be sterilized, (2) removing peroxide from the material to be sterilized, and only after the removal of the peroxide, (3) irradiating the material with UV light. Without hindsight of the presently claimed invention, there is no suggestion in KODERA, DIGERONIMO or LOLIG ER, considered singularly or in combination, as to why one should proceed in accordance with the presently claimed invention. This is because it was not known until the present inventor's discovery that even when hydrogen peroxide is removed from a packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light.

Therefore, claim 4 is believed to be unobvious over the references cited by the Examiner and withdrawal of this rejection is respectfully requested.

**THE EXAMINER'S OBVIOUSNESS REJECTION OF**

**CLAIMS 2-3, 5, 15, 17, AND 21-26**

Claims 2-3, 5, 15, 17, and 21-26 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over KODERA in view of DIGERONIMO.



**Claims 15, 21, 23, and 26**

In making the rejection on page 4 of the Office Action, the Examiner has reversed the sequence disclosed by KODERA (when there is no teaching in any of the cited references to do so). KODERA specifically teaches that the drying means are located after the ultra-violet-ray sterilization means. More particularly, KODERA teaches and claims a sterilization apparatus comprising a plurality of housings communicatively connected in sequence:

- hydrogen peroxide sterilizing means
- ultra-violet-ray sterilization means in a housing downstream in said travel direction from the hydrogen peroxide sterilizing means
- drying means in a housing downstream from the ultra-violet-ray sterilization means.

Again, it is emphasized that there is no suggestion in KODERA to locate the drying means upstream of the ultra-violet-ray sterilization means nor any other teaching that would lead one of ordinary skill in the art to practice the claimed invention, without hindsight of the present invention.

Here, like the obviousness rejection of claim 4 discussed above, the Examiner has improperly attempted to satisfy an element of applicant's claimed invention by arguing an "intrinsic" feature, *i.e.*, "that the microorganisms present on the surfaces of the packaging sheet material in the Koder reference intrinsically absorb the residual hydrogen peroxide left after the step of drying." OFFICE ACTION at 4. Since the term "intrinsically" means nothing more than "inherency" and inherency is not the proper standard for obviousness, a proper *prima facie* case of obviousness has not been established. Further, contrary to the Examiner's assertion, there are no

microorganisms left on the material at the drying step in the KODERA patent. This is because the web has been previously subjected to hydrogen peroxide sterilizing means, and ultra-violet-ray sterilization means in a housing downstream in said travel direction from the hydrogen peroxide sterilizing means, whereby to create microorganism-killing synergy between peroxide and UV upstream of the drying means.

Applicant agrees with the Examiner's comment that "the Koder reference teaches the importance of the synergistic effect produced by the combination of hydrogen peroxide and UV (col. 1, lines 13-18)." This is precisely why KODERA never offers any teaching or even a suggestion regarding removing the peroxide by drying, prior to irradiating with UV. If it is so important to seek the synergistic effect produced by the combination of peroxide and UV, one of ordinary skill in the art would not even consider removing the peroxide prior to irradiating with UV. This is clear proof of unobviousness of the claimed invention.

The Examiner has asserted on page 5 of the Office Action that "the Koder process and apparatus provide for a trace quantity of hydrogen peroxide for its interaction with the UV light." In reality, however, the KODERA process and apparatus, mist supply pipes 13 are provided to supply mist into the chamber 12 where droplet particles approximately 10 microns in diameter adhere to both sides of the material to be sterilized, prior to irradiation by UV light to effect sterilization, and successive drying. There is not a teaching or suggestion in KODERA to dry the peroxide-coated material prior to irradiating only a trace quantity with the ultra-violet-ray sterilization means, in the manner disclosed and claimed in the present application. Moreover, prior to the presently claimed invention, it was not known that

even when hydrogen peroxide is removed from a packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light (see Annex 1 and Annex 2).

In connection with claim 15, the Examiner has argued "the Koder reference discloses the use of tank for immersing the packaging sheet in liquid hydrogen peroxide without providing its intrinsic depth measurements; however, determining the proper depth depends on the dimensions of the thickness of the packaging material, i.e, very thick laminates require a deeper bath. This is an obvious matter of choice of design within the scope of the artisan". OFFICE ACTION at 5. Contrary to the Examiner's assertion, bath depth is not influenced by web thickness; but it is affected by web speed. The faster the web travels, the deeper the bath must become to ensure a sufficient residence time of the web in the bath to enable the sterilization process. In high-speed packaging machines such as Tetra Pak's commercially available TBA/21 packaging machine, the U-shaped peroxide bath had a depth of 1.9 meters per side, giving a total immersion of 3.8 meters of packaging material web. In the commercially available Tetra Pak A3 packaging machine, the U-shaped peroxide bath has a depth of 1.5 meters per side, giving a total immersion of 3 meters of packaging material web. In accordance with the invention, the UV lamp can be located downstream of the drying section constituted by an air knife in these packaging machines, with beneficial effects on the sterilization system. It can also be used in machines with baths as shallow as 50cm as claimed in claim 15. If one applied the technique of KODERA in a machine having a bath only 50cm deep, at normal industrial production speeds the material would not have a sufficient

residence time to effect the sterilization process, and only by slowing down the process itself could sterilization be achieved.

In connection with claims 15, 21, 23 and 26, the Examiner has attempted to combine the disclosure of DIGERONIMO for the purpose of modifying "the method of the Koderia reference by irradiating at 254 nm as taught by the DiGeronimo reference since the lamp at such a wavelength operates at 99.9% efficiency (col.2, lines 50-52)." OFFICE ACTION at 5. However, even if one modified the apparatus of KODERA to include the 254nm UV lamps of DIGERONIMO, the resulting apparatus would still not operate with the claimed sequence of steps, *i.e.*, (1) applying peroxide to a material; (2) removing peroxide, and only after the removal of the peroxide; and (3) irradiating the material with UV light. Without hindsight of the claimed invention, there is no suggestion in the prior art as to why one should proceed in this way, because it was not known that even when hydrogen peroxide is removed from a packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light. Reference is again made to Annex 1 and Annex 2.

#### **Claims 5 and 22**

On page 5-6 of the Office Action, with regard to claims 5 and 22, the Examiner has once again isolated portions of the KODERA patent and combined them in a way that is completely out of context when the KODERA patent is considered in its entirety. The Examiner has also reversed the sequence disclosed by KODERA (when there is no teaching in any of the cited references to do so). KODERA does not remove peroxide by drying prior to irradiation by UV. On the contrary, KODERA specifically teaches that the drying means are located after the

ultra-violet-ray sterilization means, *i.e.*, a sterilization apparatus comprising a plurality of housings communicatively connected in sequence:

- hydrogen peroxide sterilizing means
- ultra-violet-ray sterilization means in a housing downstream in said travel direction from the hydrogen peroxide sterilizing means
- drying means in a housing downstream from the ultra-violet-ray sterilization means.

The Examiner also states that “the Koder reference teaches the importance of the synergistic effect produced by the combination of hydrogen peroxide and UV (col. 1, lines 13-18)”. OFFICE ACTION at 6. This is precisely why it would have been unobvious to one of ordinary skill in the art to remove the peroxide prior to irradiating with UV. Without the present inventor's discovery that even when hydrogen peroxide is removed from a packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light, it is unobvious to proceed in the manner claimed in the present application.

The Examiner has also taken the teaching of the prior art out of context when he states that “the Koder process and apparatus provide for a trace quantity of hydrogen peroxide for its interaction with the UV light.”. OFFICE ACTION at 6 (emphasis added). On the contrary, KODERA teaches (see column 3, lines 57-61) that “[t]he germicidal liquid 19 thus acted on by the ultrasonic waves is induced by the dispersive action thereof to assume a spiral-like form 20 resembling that of water in a waterspout and, further, the form of a fog, that is, an H<sub>2</sub>O<sub>2</sub> mist of low concentration at room temperature” and (see column 4, lines 13-16) “entering the

chamber 26 through an inlet pipe 27, passes out of the chamber 26 through a discharge pipe 28". See also column 1, line 68 et seq. which describes "a thin film of hydrogen peroxide . . . is applied onto outer surfaces of material." The expression trace quantity is clearly used in the application to refer to a quantity present after drying and that is so small that it can even be absorbed by a microorganism, not a quantity that is several orders of magnitude greater such that it can be piped into and out of sterilization chambers to form a thin film on the surfaces of the material to be sterilized in the manner taught by KODERA.

With respect to claims 5 and 22, if (as proposed by the Examiner on page 6 of the Office Action) the apparatus of KODERA were modified to include the 254nm UV lamps of DIGERONIMO, the resulting apparatus would still not operate with the claimed sequence of steps, *i.e.*, (1) applying peroxide to a material; (2) removing peroxide, and only after the removal of the peroxide; and (3) irradiating the material with UV light. There no teaching or suggestion in the prior art that it could work in the manner claimed in claims 5 and 22, because prior to the present invention, it was not known that even when hydrogen peroxide is removed from a packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light.

**Claims 2-3, 17, 24, and 25**

These dependent claims are unobvious over KODERA in view of DIGERONIMO for the same reasons and considerations discussed above for the claims from which claims 2-3, 17, 24, and 25 depend.

In view of the above, claims 2-3, 5, 15, 17, and 21-26 are believed to be unobvious over the references cited by the Examiner and withdrawal of this rejection is respectfully requested

**THE EXAMINER'S OBVIOUSNESS REJECTION OF CLAIM 6**

Claim 6 has been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over KODERA in view of DIGERONIMO as applied to claim 21 and further in view of LAGUNAS-SOLARE.

Applicant's comments with respect to KODERA in view of DIGERONIMO as discussed above are herein incorporated by reference. The Examiner has further combined LAGUNAS-SOLARE to show methods of microbial disinfection. However, even if one of ordinary skill in the art modified the apparatus of KODERA, to carry out surface disinfection as taught by LAGUNAS-SOLARE one could still not deduce therefrom the invention as claimed in the present application.

Therefore, claim 6 is believed to be unobvious over the references cited by the Examiner and withdrawal of this rejection is respectfully requested.

**THE EXAMINER'S OBVIOUSNESS REJECTION OF CLAIMS 18 AND 27**

Claims 18 and 27 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over KODERA in view of DIGERONIMO as applied to claim 26 and further in view of CASTBERG.

Applicant's comments with respect to KODERA in view of DIGERONIMO as discussed above are herein incorporated by reference. The Examiner has further combined CASTBERG to show the use of an excimer lamp. However, even if one of ordinary skill in the art modified the apparatus of KODERA using UV lamps as taught

by DIGERONIMO in the form of excimer lamps as taught by CASTBERG, one could still not deduce therefrom the invention as claimed in the present application.

Therefore, claims 18 and 27 are believed to be unobvious over the references cited by the Examiner and withdrawal of this rejection is respectfully requested.

### **CONCLUSION**

In summary, the prior art documents cited by the Examiner, considered singularly or in combination, fail to teach or suggest the sequential combination of steps claimed in this application, *i.e.*, (1) applying peroxide to a material to be sterilized; (2) removing peroxide from the material to be sterilized, and only after the removal of the peroxide; and (3) irradiating the material with UV light. The prior art also fails to recognize that even when hydrogen peroxide is removed from the packaging material by drying, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light, and therefore the skilled artisan had no reason to believe that the sequential steps claimed in the present application could function. As such each of the rejections under 35 U.S.C. § 103(a) should be withdrawn.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

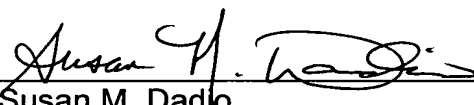


In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,

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